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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,348	08/15/2003	Keith K. Daellenbach	BJT 332B	1593

23581 7590 01/04/2006

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

DATE MAILED: 01/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/642,348	DAELLENBACH, KEITH K.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 12-1-05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

Examiner acknowledges that claim 12 has been cancelled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2-6, 11, 18, 21, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by WIPO publication WO 00/72908 to Micro-Heart.

In reference to claim 1 Micro-Heart discloses a needle-free injection device for delivering a fluid into an internal organ comprising: a rigid end effector including at least one orifice, the end effector having a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its longitudinal axis during use (page 18, lines1-7; page 4, lines 11-13); further comprising a fluid reservoir (page 13, lines 28-29) in fluid communication with the end effector and an ejection mechanism that ejects fluid from the reservoir through the end effector and out the injection orifice with sufficient pressure to penetrate the tissue of interest (page 2, lines 9-19 and lines 25-30), use on prostate tissue being an intended use by Applicant.

In reference to claims 2-6 Micro-Heart discloses a device in which the rigid end effector (Fig. 4) has a straight shaft (16), distal section (34), all injection orifices located

in the distal section (32), and the ejection mechanism allows the device to eject multiple doses without refilling the reservoir (page 12, lines 12-17).

In reference to claim 11, Micro-Heart discloses a needle-free injection device for delivering a fluid into an internal organ comprising: a fluid reservoir (page 13, lines 28-32), a longitudinally rigid extension structure wherein the extension structure is sufficiently rigid to maintain a longitudinal shape during use (Fig. 12, wherein the longitudinal rigid extension is formed betwee1204 and 1206; also described in page 18, lines 1-7). The device also comprises a distal region with a partially hollow interior in fluid communication with the reservoir (page 2, lines 9-15 and page 13, lines 28-32), as well as an ejection mechanism to eject fluid through the injection orifices in the distal region with sufficient structure to penetrate the target tissue (page 2, lines 9-19).

In reference to claim 18, Micro-Heart discloses a needle-free injection device for delivering a fluid into a selected internal tissue comprising: a rigid end effector with at least one injection orifice, the end effector being adapted to be positioned with the injection orifice adjacent the selected internal tissue (page 2, lines 9-19), wherein the end effector has a longitudinal axis configured into a shape wherein the end effector is sufficiently rigid to maintain the shape of its axis during use (page 18, lines 1-7). Micro-Heart further discloses a fluid reservoir (page 13, lines 28-32) and an ejection mechanism that may be adjusted to provide an appropriate system pressure for the internal tissue (page 12, line 12-16).

In reference to claims 21, 23 and 24, Micro-Heart discloses a blunt distal end (page 2, lines 9-12), as well as the longitudinal axis of the end effector being generally straight (Fig. 2a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Micro-Heart (WO 00/72908). Micro-Heart discloses the device substantially as claimed except for the fluid of injection being ethanol. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device of Micro-Heart to include the injection of ethanol because Applicant has not disclosed that ethanol provides an advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with ethanol because Micro-Heart discloses the injection of medicinal fluids, and ethanol is a fluid that is able to be injected with the Micro-Heart device, just as the device injects other fluids. Therefore it would have been an obvious matter of design choice to modify Micro-Heart to obtain the invention as specified in claims 7 and 13.

Claims 8-10, 14-17, 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Micro-Heart in view of Paskar (US Patent No. 6,623,449). Micro-

Heart discloses the device substantially as claimed, including injection orifices along the length of the end effector/extension structure and therefore lateral to the longitudinal axis of the distal region of the end effector/extension structure (page 2, lines 29-30), however, Micro-Heart does not disclose expressly that the injection orifices are arranged linearly, in multiple rows and in offset rows. Paskar discloses a needle-free jet injection device with injection orifices that are arranged linearly in multiple offset rows along the length of the end effector/extension structure (Figs. 16 and 16a). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Micro-Heart with the multiple offset rows of Paskar in order to provide a more extensive coverage area for the injection medium.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Micro-Heart in view of Kollias et al. (US Patent No. 6,251,099). Micro-Heart discloses the invention substantially as claimed including an injection mechanism in which the injection pressure can be adjusted and selected, however it does not disclose expressly a mechanism configured to provide a rise time to a peak pressure wherein the rise time and peak pressure selection are to preserve tissue functionality. Kollias, however, discloses a needleless injection device in which the peak injection pressures and rise time to these pressures can be selected in order to preserve the functionality of the tissue (col. 1, lines 55-64). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Micro-Heart with the rise time and peak pressure selections of Kollias, in order to provide a safe and customizable

device to customize the injection to each tissue being injected and therefore minimize tissue damage and preserve functionality.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LCS